



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room W-066-0609  
Silver Spring, MD 20993-0002

Medline Industries, Inc.  
% Mr. Matt Clausen  
Regulatory Affairs  
One Medline Place  
Mundelein, Illinois 60060-4486

JAN - 7 2010

Re: K093349

Trade/Device Name: Medline Curad Oil Emulsion Dressing  
Medline Curad Xeroform Petrolatum Dressing  
Medline Curad Petrolatum Gauze Dressing

Regulation Number: None  
Regulation Name: None  
Regulatory Class: Unclassified  
Product Code: FRO  
Dated: December 22, 2009  
Received: December 23, 2009

Dear Mr. Clausen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

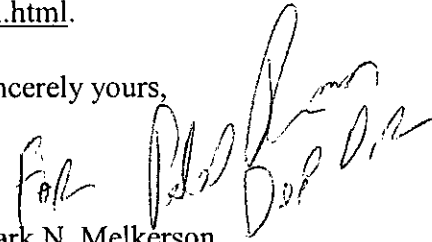
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comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/cdrh/mdr/> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Mark N. Melkerson', is written over the typed name.

Mark N. Melkerson  
Director  
Division of Surgical, Orthopedic  
and Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K093349

Device Name:

**Medline Curad Xeroform Petrolatum Dressing**

Indications for Use:

The intended use is as a wound dressing layer for skin graft recipient sites, newly sutured wounds, abrasions, lacerations and minor or partial thickness burns. These dressings may also be used as an initial layer for wounds with light exudates where deodorization is desired.

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use             
(21 CFR 801 Subpart C)

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OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krane

(Division Sign-Off)

Division of Surgical, Orthopedic,  
and Restorative Devices

(6)

510(k) Number K093349

## Indications for Use

510(k) Number (if known): K093349

Device Name:

**Medline Curad Petrolatum Gauze Dressing**

Indications for Use:

**These dressings are intended for use as a primary layer for donor sites, skin graft recipient sites and minor burns. These dressings may also be used as an initial layer for surgical incision sites and as a seal around tubes and drains exiting the body.**

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE  
OF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krane  
(Division Sign-Off)  
Division of Surgical, Orthopedic,  
and Restorative Devices

(7)

510(k) Number K093349

## Indications for Use

510(k) Number (if known): K093349

Device Name:

**Medline Curad Oil Emulsion Dressing**

Indications for Use:

**These dressings are intended for use as a primary dressing in the management of light to medium draining wounds such as minor burns, abrasions and lacerations. These dressings may also be used under the care of a health care professional for heavy draining wounds such as surgical incisions, skin grafts and dermal ulcers.**

Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use X  
(21 CFR 801 Subpart C)

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OF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krane

(Division Sign-Off)

Division of Surgical, Orthopedic,  
and Restorative Devices

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510(k) Number K093349